IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	)	
Plaintiffs,	)	C.A. No. 08-91 (GMS)
v.	)	
COREVALVE, INC. and MEDTRONIC COREVALVE LLC,	)	REDACTED - PUBLIC VERSION
Defendants.	)	

EDWARDS' OPENING BRIEF IN SUPPORT OF THEIR MOTION FOR ENHANCED DAMAGES PURSUANT TO 35 U.S.C. § 284

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NATURE AND STAGE OF PROCEEDINGS

On April 1, 2010, after less than four hours of deliberation, the jury returned a verdict that CoreValve literally and willfully infringed the Andersen '552 Patent owned by Edwards.[1] D.I. 313 at 2-3. The jury rejected CoreValve's sole invalidity defense (non-enablement), its de minimis damages position and its claim of "independent development." *Id.* at 4. Significantly, CoreValve offered no proof of reliance on advice of counsel. Trial Tr. ("TT") at 1200:24-1201:18. The jury awarded Edwards lost profits of $72.65 million and a reasonable royalty of $1.28 million. *Id.* at 5. Edwards now moves the Court to treble the award. 35 U.S.C. § 284.

SUMMARY OF ARGUMENT

Edwards requests that the Court award treble damages under 35 U.S.C. § 284 for two reasons. First, because the jury found CoreValve willfully infringed Edwards' patent. Second, because each of the well-known *Read* factors supports treble damages:[2]

1. CoreValve knew of Edwards' patent and willfully infringed it.

2. CoreValve lacked a good faith belief of invalidity or noninfringement of Edwards' patent. CoreValve founder and CEO Dr. Seguin told financial investors that Edwards' patent was "very strong." Further, CoreValve presented no evidence of an opinion of counsel.

3. CoreValve refused to follow the Court's *Markman* construction of "cylindrical." CoreValve's own internal, pre-suit documents contradicted its litigation position

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[1] As used herein, "Edwards" refers to Edwards Lifesciences AG and Edwards Lifesciences LLC, and "CoreValve" refers to CoreValve, Inc. and Medtronic CoreValve, LLC, and "'552 Patent" refers to U.S. Patent No. 5,411,552.

[2] *Read Corp.* v. *Portec, Inc.*, 907 F.2d 816, 826-27 (Fed. Cir. 1992).

on "cylindrical." CoreValve forced Edwards to waste resources on unsupportable defenses, which CoreValve then abandoned at the last minute.

4. Medtronic, which owns CoreValve, has assets of $25.2 billion and annual revenues of $14.6 billion. These companies can easily pay a treble damages award.

5. Infringement, willfulness, validity and damages were not close questions, as the jury returned a verdict for Edwards on all issues after less than four hours of deliberation.

6. CoreValve engaged in infringing activities for years and continues to infringe today.

7. CoreValve took no remedial action to reduce or eliminate the impact of its infringement. Instead, CoreValve recklessly continued its course of willful infringement.

8. CoreValve was motivated to harm Edwards by using the Andersen invention in order to take sales away from Edwards.

9. CoreValve concealed the extent of its misconduct before beginning to sell its Generation 3 devices.

STATEMENT OF FACTS

The relevant facts are set forth in the Argument section below.

ARGUMENT

I. THE JURY'S FINDING OF WILLFUL INFRINGEMENT SUPPORTS TREBLE DAMAGES

Because the jury found that CoreValve willfully infringed Edwards' patent, the Court may award enhanced damages. *In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007). The past damages awarded by the jury are meant to compensate Edwards for the sales it would have made absent CoreValve's infringement, as well as a royalty on CoreValve's remaining sales. Where, as here, the infringement was willful, punitive damages are appropriate. *See SRI Int'l, Inc.* v. *Advanced Tech. Labs., Inc.*, 127 F.3d 1462, 1464 (Fed. Cir. 1997) ("[35

U.S.C. § 284] recognizes the tortious nature of patent infringement and the public interest in a stable patent right, for enhanced damages are not compensatory but punitive.").

To summarize the facts: CoreValve was founded to sell a single product that infringed its sole competitor's patent, which CoreValve's CEO described as "very strong." TT at 605:3-5; D.I. 313 at 3. Despite a warning letter from Edwards regarding the '552 patent, CoreValve manufactured in the U.S. as many devices as it could, as fast as it could. Not one CoreValve attorney or venture capital attorney testified at trial that CoreValve obtained or relied on advice of counsel. TT at 1200:24-1201:18. CoreValve did not change the design of the Generation 3 device, nor did it move manufacturing overseas. TT at 997:15-25, 1402:9-15. Instead, CoreValve decided to "double down" in Irvine and build a large new plant across the street from its existing facility. TT at 997:15-25, 1409:5-11. CoreValve then executed its planned "exit strategy" by selling the company to Medtronic for $700 million, plus possible additional payments up to $150 million. TT at 921:7-922:13. Medtronic knew of the lawsuit, knew of the risks [redacted]. TT 930:8-21; [redacted]. Medtronic purchased CoreValve to continue willfully infringing Edwards' patent, increase sales of the CoreValve device, and then try to switch to foreign production when CoreValve was found to infringe. Terranova Decl., Ex. B. As a result of CoreValve's illegal and willful conduct, Edwards must now face a huge competitor that is producing devices at full capacity. Had it respected Edwards' patent rights, CoreValve would be much further behind. Past damages will not adequately punish CoreValve and Medtronic. Such conduct warrants treble damages.

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[3] Declaration of Christopher Terranova, submitted herewith.

II. THE *READ* FACTORS WEIGH HEAVILY IN FAVOR OF TREBLE DAMAGES

Under 35 U.S.C. § 284, "the court may increase the damages up to three times the amount found" by the jury. The purpose of increased damages is to deter willful infringement. *E.g.*, *Mathis* v. *Spears*, 857 F.2d 749, 754 (Fed. Cir. 1988). "[T]he principal considerations in enhancement of damages are the same as those of the willfulness determination, but in greater nuance as may affect the degree of enhancement." *SRI Int'l*, 127 F.3d at 1469.

To determine whether to award enhanced damages, courts weigh a list of factors, called the "*Read* factors": "(1) whether the infringer deliberately copied the ideas or design of another; (2) whether the infringer, when he knew of the other's patent protection, investigated the scope of the patent and formed a good-faith belief that it was invalid or that it was not infringed; (3) the infringer's behavior as a party to the litigation; (4) the infringer's size and financial condition; (5) the closeness of the case; (6) the duration of the infringer's misconduct; (7) any remedial action by the infringer; (8) the infringer's motivation for harm; and (9) whether the infringer attempted to conceal its misconduct." *Finjan Software, Ltd.* v. *Secure Computing Corp.*, Civ. A. No. 06-369-GMS, 2009 U.S. Dist. LEXIS 72825, at *47-48 (D. Del. Aug. 18, 2009) (citing *Read Corp.* v. *Portec, Inc.*, 970 F.2d 816, 826-27 (Fed. Cir. 1992)).

A careful consideration of the *Read* factors, below, demonstrates that CoreValve's conduct warrants the maximum allowable increase in damages.

Factor 1. CoreValve Knew of Edwards' Patent and Willfully Infringed

At trial, Dr. Seguin testified that in the early 1990s – he could not remember exactly when – he had an idea for a percutaneous heart valve. TT at 1226:20-24. He did not, however, have a single document corroborating his story. *Id.* at 1226:25-1227:1. He admitted that he did not know how to do it at the time. *Id.* at 1227:2-4. The evidence showed that Dr. Seguin's first documented activity occurred in 1996, when he obtained a copy of Edwards'

patent. *Id.* at 1226:17-19; [redacted]. When he hired an engineering company, he was able to develop an infringing product in six months. TT at 1059:17-1060:8. The jury rejected CoreValve's attempt to paint its conduct as an "independent development" that did not use Edwards' patent and that CoreValve "went in a different direction." D.I. 313; TT at 225:8-18. The jury, applying the *Seagate* standard, D.I. 311 at 23, found that Edwards proved by clear and convincing evidence that CoreValve willfully infringed. D.I. 313 at 3. It determined that there was an "objectively high risk" that CoreValve's actions were infringing, and that CoreValve knew or should have known of that objectively high risk. D.I. 311 at 23. This conduct supports enhanced damages. A district court should "defer[] to the jury's finding in this regard [and] not substitute its own findings for those made by the jury." *Finjan*, 2009 U.S. Dist. LEXIS 72825, at *48-49 (citing *Jurgens* v. *CBK, Ltd.*, 80 F.3d 1566, 1572 (Fed. Cir. 1996)).

Factor 2. CoreValve Did Not Have a Good Faith Belief that Edwards' Patent Was Invalid or Not Infringed

CoreValve knew or should have known that it was infringing Edwards' patent. CoreValve knew of the patent long before it began manufacturing the infringing devices. Dr. Seguin, a founder of CoreValve, obtained a copy of the patent in 1996 and Georg Bortlein, the other founder, got a copy in 2001. TT at 1063:8-13, 1226:17-19. After Mr. Bortlein read the patent, he obtained a copy of the inventors' 1992 article in the European Heart Journal, studied it and discussed it with Dr. Seguin. *Id.* at 1065:4-19. Mr. Bortlein thought this "was definitely an important publication." *Id.* at 1066:1-9.

CoreValve was on notice that it was infringing the Andersen patent, but did not change its conduct. In April 2005, Edwards sent a letter to Dr. Seguin at CoreValve stating that CoreValve's device likely was infringing and requesting an "explanation." Terranova Decl., Ex. D (PTX 155). Neither Dr. Seguin nor anyone else ever responded to the letter. TT at 1236:6-10.

Less than three months later, Dr. Seguin held a conference call with financial investors. *Id.*, [redacted]. On the call, he told the financial community that "very clearly, the Andersen patents have been shown as being a very strong patent." TT at 1242:6-1243:1, 1243:20-1244:5.

Aside from Dr. Seguin's and Mr. Bortlein's self-serving assertions at trial that they did not believe their device infringed the Andersen patent – which the jury rejected – CoreValve presented no evidence of a good faith belief. CoreValve presented no evidence that Dr. Seguin, Mr. Bortlein or CoreValve ever received an opinion of counsel regarding this "very strong patent" – much less a well-reasoned opinion. Not one CoreValve or venture capital attorney came forward to testify for CoreValve. The Court asked CoreValve's counsel twice whether it was "relying on advice of counsel." TT at 1200:24-1201:18. Twice, counsel responded "No." *Id.* CoreValve's lack of a single attorney opinion sufficiently persuasive and well-reasoned to present to the jury supports an award of enhanced damages. *See, e.g.*, *Finjan*, at 2009 U.S. Dist. LEXIS 72825, at *49 (holding that although defendant has no duty to obtain opinion of counsel, lack of evidence of such opinion weighs in favor of enhancing damages).

The jury found that CoreValve continued selling its infringing device for years, despite an "objectively high likelihood" that its actions infringed the Andersen patent. D.I. 313 at 3. Such conduct supports enhanced damages. *E.g.*, *Finjan*, at 2009 U.S. Dist. LEXIS 72825, at *49 (granting enhanced damages because the "record evidence suggests that [defendant] knew or should have known that it was likely infringing [plaintiff]'s patents"); *i4i Ltd. Partnership* v. *Microsoft Corp.*, 598 F.3d 831, 858-59 (Fed. Cir. 2010) (affirming enhanced damage award because defendant "was aware of [plaintiff]'s patent, never formed a good faith belief of noninfringement, and clearly intended to [create a product] with similar capabilities to [plaintiff]'s patented products").

Factor 3. CoreValve's Litigation Conduct Supports an Award of Treble Damages

a. CoreValve Refused to Follow the Court's Claim Construction of "Cylindrical"

On May 27, 2009, the Court issued its claim construction Order, defining the term "cylindrical support means" as "a portion of the stent supporting the valve that has a shape of or relating to a cylinder." *Markman* Order, D.I. 109 at 2. CoreValve did not move for reargument under Local Rule 7.1.5. Instead, it waited until September 22, 2009 – nearly four months after the Court's Order – to request "clarification of the Court's view of the meaning" of "cylindrical" and "cylinder." D.I. 156 at 3. The Court denied this motion. D.I. 191.

Still not deterred, CoreValve argued in a subsequent motion *in limine* that the "cylindrical" shape is relevant only "*before* implantation." D.I. 205 at 1 (emphasis in original). The Court rejected CoreValve's attempt to import such a limitation not in the claim, stating that "[t]he court rejects CoreValve's proposed construction because such a temporal limitation is not supported by the specification or the prosecution history." D.I. 280 at 2.

In their expert reports and during their depositions, CoreValve's expert witnesses rejected the Court's claim construction. Instead, they applied CoreValve's definition, namely that "cylindrical" means a cylinder having a constant diameter along its length. [redacted]

[redacted]

Before trial, the Court warned CoreValve:

> I expect counsel will instruct your witnesses in your prep. This is not something it is wise for an expert to do, deviate from the Court's claim construction.

Feb. 16, 2010 Pretrial Conf. Tr. at 40:3-6.[4] CoreValve's counsel promised, "We don't have any intention of doing that, Your Honor." *Id.* at 40:7-8.

At trial, however, CoreValve's expert witnesses did just that. Dr. Rothman used CoreValve's definition of "cylindrical," rather than the Court's. He testified on direct examination that "cylindrical" means a shape with "parallel sides or virtually parallel sides." TT at 1636:23-1637:3. Using this definition, he argued that CoreValve's device does not infringe because "the base of the CoreValve is not intended to be a cylinder, by mistake, misshapen. It's intended to be a cone." *Id.* at 1637:4-6. Even on cross-examination, when asked about the Court's claim construction, Dr. Rothman adhered to CoreValve's definition:

> **Q:** And is it your testimony that when the claim calls for something cylindrical, it means a perfect right cylinder?
>
> **Dr. Rothman:** Well, I tend to think of a cylinder having a distance between the sides, the opposite sides, the diameter to remain constant.

Id. at 1693:12-16.

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[4] To punctuate its "cylindrical" construction, the Court amended its *Markman* Order, D.I. 109 at 4 n.13, to state the following about the '462 patent, which was then in the case:

> The amended order will delete [the] second sentence and read as follows: "In other words, the Court rejects the defendant's proposed construction that requires 'a diameter that is constant along the longitudinal axis.'"

Feb. 16, 2010 Pretrial Conf. Tr. at 7:1-7.

Lastly, CoreValve pressured Dr. Pinchuk, while on the stand, to change his testimony to conform to CoreValve's rejected definition of "cylindrical." Dr. Pinchuk, on cross-examination, was asked "do you agree that CoreValve's device has a cylindrical support means?" TT at 1472:3-4. Dr. Pinchuk replied, "Yes." *Id.* at 5. CoreValve, on redirect, tried to get Dr. Pinchuk to change his answer. After asking whether he remembered the question, CoreValve asked Dr. Pinchuk "let me make sure it's clear, because I heard testimony that may not have been entirely consistent. . . . Is it your opinion that the bottom portion of the CoreValve device is cylindrical?" TT at 1500:1-13. Dr. Pinchuk, realizing his mistake in departing from CoreValve's definition, then changed his testimony: "It is not cylindrical to me." *Id.* at 1500:14. As the Court said at trial, CoreValve's comment, signaling Dr. Pinchuk to change his testimony, was "inappropriate." *Id.* at 1500:7-8.

b. CoreValve's Internal Documents Stated Its Product Was "Cylindrical"

Even though CoreValve's confidential internal documents stated that its device was "cylindrical," it took a different – and unsupportable – position in the courtroom. At trial, Edwards presented a collection of over 40 CoreValve documents that "describ[ed] the CoreValve device using terms such as 'cylinder' or 'cylindrical.'" TT at 749:4-750:11, [redacted]. CoreValve did not dispute that these documents were its own, nor did it try to explain the documents. Rather, ignoring its own "cylindrical"-shape documents, CoreValve tried to recast its device as "two cones," TT 1819:22-24.

c. CoreValve Forced Edwards to Waste Resources on Unsupportable Defenses that CoreValve Dropped at the Last Minute

i) CoreValve Dropped Its Safe Harbor Defense the Day Before the Proposed Pretrial Order Was Due

In April 2008 Answer, CoreValve pleaded the safe harbor defense: that its activities in the U.S. were noninfringing under 35 U.S.C. § 271(e)(1). D.I. 12 at 6. [redacted]

However, on January 25, 2010, the day before the proposed pretrial order was due, CoreValve, without explanation, abandoned the defense. Pretrial Conf. Tr. at 14:12-15:18. By that time, Edwards had taken vast discovery on the issues, retained an expert and submitted an expert report, taken and defended expert depositions, analyzed and prepared statements of uncontested facts, contested issues of fact and law, expert qualifications, an exhibit list, deposition designations, a trial brief, a verdict form and jury instructions – all of which related to the safe harbor issue. D.I. 250. After all this work to prepare for trial had been completed, CoreValve simply dropped the defense.

Moreover, CoreValve maintained this defense, for nearly two years, without basis. CoreValve knew that it could not show that each and every objective "use" for which it manufactured the otherwise-infringing device would "contribute, relatively directly, to the generation of the kinds of information that are likely to be relevant in the [FDA approval process]," as required by the law. *Merck KGAA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193,

200 (2005); *Amgen, Inc.* v. *Int'l Trade Comm'n*, 565 F.3d 846, 852-53 (Fed. Cir. 2009). In particular, it was clear that CoreValve wanted to sell in Europe as many infringing devices as it could, as fast as it could. And indeed it did. [redacted] The devices were manufactured in the U.S. not to collect data for the FDA, but to make money [redacted]

CoreValve's contemporaneous documents confirm its plan to commercialize and exit, not simply obtain FDA approval. [redacted]

Overseas sales, not data collection, were at the heart of CoreValve's business strategy.

ii) CoreValve Dropped All of Its Invalidity Defenses Except Enablement at 9:00 p.m. the Night Before Trial Began

CoreValve's decision to drop the safe harbor defense at the last moment was not an isolated incident. At 9:00 p.m. on the night before trial began, CoreValve called Edwards to give notice that it was abandoning all of its invalidity defenses except enablement. TT at 2:14-3:9. Anticipation, obviousness and written description were all dropped. CoreValve had raised these defenses in its Answer in April 2008, forcing Edwards to waste time preparing for them for almost two years.

CoreValve maintained these defenses although they clearly lacked support. For example, CoreValve asserted Ersek U.S. Patent No. 3,657,744 as prior art, even though shortly

after CoreValve filed its Answer, Judge Sue Robinson held that Ersek's invention "was not meant to be, nor could it be, delivered intraluminally [through the vascular system]. To argue otherwise defies the common sense approach" explained by the Supreme Court. *Cordis Corp.* v. *Boston Sci. Corp.*, 576 F. Supp. 2d 645, 650 (D. Del. 2008) (citing *KSR Int'l Co.* v. *Teleflex, Inc.*, 550 U.S. 398 (2007)). Nevertheless, CoreValve continued asserting Ersek as prior art. *See* App. A (chart of CoreValve's prior art). Such litigation conduct supports an award of treble damages. *i4i Ltd.*, 598 F.3d at 859 ("acts that unnecessarily prolong litigation" support enhanced damages).

CoreValve claimed that it dropped its invalidity defenses at the last minute because of the Court's ruling excluding the '462 patent from trial. TT at 3:5-9. The facts are otherwise. CoreValve asserted, and for two years continued to assert, all of the defenses – and all of the prior art – against the '552 patent. *See* App. A. The Court's ruling on the '462 patent had nothing to do with the '552 prior art defenses.

Factor 4. Medtronic's Large Size, Global Operations and Gross Revenues Support an Award of Enhanced Damages

Given Medtronic's large size, global operations, $14.6 billion annual revenue and $25.2 billion in total assets, it can "financially withstand an enhancement in damages." *Finjan*, at 2009 U.S. Dist. LEXIS 72825, at *50.

Medtronic acquired CoreValve with its eyes open to a potential liability in this case, and with all of its resources available to fight Edwards' lawsuit. Medtronic attorneys signed confidentiality undertakings and participated in the defense. Terranova Decl., Ex. L. Its principal technical witness, Dr. Rothman, is now a Medtronic employee. TT at 1652:14-1653:13. [redacted]

[redacted] "[u]nder Medtronic's large[r] sales force, CoreValve has been launched in Latin America, Australia, and Eastern Europe." *Id.*, Ex. M (Citigroup Report). Medtronic even boasted that its "scale and expertise" would "accelerate the use" of CoreValve's ReValving system. *Id.*, Ex. N.

Medtronic is one of the largest medical device companies in the world. It "operates from more than 250 manufacturing facilities, sales offices, research centers, education centers, and administration facilities that serve customers and patients in 120 countries." Terranova Decl., Ex. O. At the end of 2009, Medtronic had 41,158 full-time equivalent employees – more than 6 times the number of Edwards employees (6,400). *Id.*, Ex. P (Edwards and CoreValve 2009 Annual Reports).

Medtronic's revenue far exceeds Edwards'. For the third quarter of fiscal year 2010, which ended January 29, 2010, Medtronic reported "revenue of $3.851 billion, a 10 percent increase over third quarter revenue reported a year ago." Terranova Decl., Ex. Q (Feb. 23, 2010 News Release). In contrast, Edwards reported revenue of $340.5 million for the quarter ending March 31, 2010, which is less than 10% of Medtronic's quarterly revenue. *Id.*, Ex. R (April 20, 2010 News Release).

For a company with $14.6 billion in annual revenue, and which paid $700 million to buy CoreValve, the $74 million jury verdict is tiny. The verdict clearly had little effect on Medtronic. Shortly after the jury found CoreValve was a willful infringer, Medtronic defiantly proclaimed to financial investors that "[t]his jury verdict has no bearing on Medtronic's ability to sell Core Valve products." *Id.*, Ex. B.

Nor would treble damages burden Medtronic. It paid over 3 times that amount to purchase CoreValve last year, and each week has greater revenues than a treble damages award. Medtronic's considerable size, healthy financial condition, and dismissive statements to the financial community about the jury's verdict support enhanced damages.

Factor 5. Infringement, Willfulness, Validity and Damages Were Not Close Questions

This was not a close case. The facts in the case were strongly against CoreValve. The jury, after less than four hours of deliberation, returned a verdict for Edwards on every issue, and awarded nearly all of the damages Edwards requested. D.I. 313.

Literal infringement was not a close question. Dr. Nigel Buller, Edwards' expert, divided Claim 1 of the Edwards patent into 12 parts. TT at 776:14-19. He found each and every part in CoreValve's Generation 3 product. *Id.* at 776:20-777:7. CoreValve's experts agreed for 11 parts, contesting only one part: "projecting in a direction generally parallel." TT at 1461:8-22, 1469:15-1472:7 (Dr. Pinchuk); *id.* at 1688:5-1691:18 (Dr. Rothman). For this part of Claim 1, rather than argue about the claim language, CoreValve tried to read words into the claim to limit its meaning, such as "projections," "posts," "protrusions," and "towers." TT at 250:11-251:12, 262:2-5. However, on cross-examination, CoreValve's experts admitted these words were not in the claim. *E.g.*, *id.* at 1457:1-18, 1462:15-1463:8. Additionally, CoreValve improperly focused on only one point of the commissural supports on the Generation 3 device. To use Dr. Buller's "fork" analogy, CoreValve focused on whether the neck of the fork was "generally parallel" to the longitudinal axis, not whether the entire fork – the commissural support – was "projecting in a direction generally parallel." *Id.* at 1619:23-1620:25. Finally, CoreValve asserted that the Generation 3 device was an "integral structure," so the entire frame was a commissural support. *Id.* at 1445:1-18. This defense, too, failed, when Dr. Rothman

admitted that the preferred embodiment in Fig. 1 of Edwards' patent also was an integral structure. *Id.* at 1687:4-1688:2. In sum, CoreValve disputed infringement of only one part of Claim 1, and its arguments were not convincing enough to make it a close question.

Nor was willfulness a close question. The jury returned a verdict of willful infringement, expressly rejecting the entirety of CoreValve's defenses. D.I. 313. As discussed above, there is overwhelming evidence that CoreValve failed to pursue "independent development" and instead deliberately copied Edwards' invention, without a good faith belief that the patent was invalid or not infringed.

Lastly, the validity of the patent was not a close issue. At trial, CoreValve asserted only lack of enablement, and for that defense it had to surmount a raft of unfavorable statements – plus the presumption of validity under 35 U.S.C. § 282. Dr. Seguin, talking to financial analysts, called the patent "very strong." TT at 1242:6-1243:1. Dr. Cribier, who performed the first-in-man aortic valve replacement using a catheter, testified that the inventors' implants in pigs were "a great, great advance in this field of this percutaneous treatment" and were "dramatic evidence [that] it was possible to use a stent implanting a valve." *Id.* at 1280:13-1281:8, 1291:24-1292:1. Dr. Grube, CoreValve's principal doctor, described the inventors' pig studies as "successful." *Id.* at 1232:12-13. And in 1994, Dr. Bailey wrote about the inventors' "exciting work" and predicted that "[i]n ten years, we shall very probably look back on [their] pioneering work in the same way we respect the work of Hufnagel, Gruentzig, and Palmaz today." *Id.* at 1668:23-1670:15. Even CoreValve's expert, Dr. Rothman, agreed that Bailey's prediction was correct. *Id.* at 1670:11-15. Medtronic itself described the technology as "mind boggling." Terranova Decl., Ex. S (EDWARDS 234508-10). And there was empirical proof that the patent was valid: PVT "voted with [its] money" to acquire an Andersen license,

spending almost 20 percent of its Series A financing. TT at 1578:9-1579:21. Edwards also voted with its money, investing over $400 million in the Andersen patent and its THV business. *Id.* at 464:25-469:7. Without patent protection, Edwards would not have made these investments. *Id.* at 454:15-455:3. With all of this evidence, the validity of the patent as enabled was not a close question.

Factor 6. CoreValve Engaged in Infringing Activities for Years and Continues to Infringe Today

As noted, in April 2005 Edwards put CoreValve on notice about its infringement and requested an "explanation." Terranova Decl., Ex. D (PTX 155). Neither Dr. Seguin nor CoreValve responded. TT at 1236:6-10.

In March 2007, CoreValve received CE approval to sell its infringing product in Europe. Terranova Decl., Ex. T (Kinrich Timeline). For the next three years, CoreValve manufactured infringing devices in the U.S., and shipped them overseas in increasing quantities. *Id.*, Ex. T (Kinrich Timeline) [redacted] Even after Edwards sued CoreValve for infringement in February 2008, CoreValve continued its infringing conduct. Indeed, CoreValve decided to "double down" and build another, much larger, manufacturing facility in the United States. TT at 997:22-25.

For years, CoreValve willfully infringed Edwards' patent. As this court recently held, years of willful infringement "weighs in favor of enhanced damages." *Finjan*, 2009 U.S. Dist. LEXIS 72825, at *51.

Factor 7. CoreValve Did Not Take Any Remedial Action to Avoid Infringing Edwards' Patent

The Patent Laws, which allow an inventor to acquire a temporary monopoly over an invention, are designed to encourage others to "pursue innovations, creations, and new ideas

beyond the inventor's exclusive rights." *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730-31 (2002). CoreValve, however, had a different plan.

Despite Edwards' warning letter, CoreValve never changed its Generation 3 device to avoid infringement. TT at 1402:9-21. [redacted] CoreValve manufactured as many infringing devices as it could, shipped those devices overseas and then sold the company to a large medical device company, Medtronic, for an initial payment of $700 million plus additional payments up to $150 million. TT at 1210:20-1211:10.

An award of treble damages will deter future infringers from such conduct. Years of willful infringement, without any remedial action, clearly supports enhanced damages. *Finjan*, 2009 U.S. Dist. LEXIS 72825, at *51; *nCUBE Corp.* v. *SeaChange Int'l, Inc.*, 313 F. Supp. 2d 361, 390 (D. Del. 2004) (awarding enhanced damages because "remedial efforts after learning of the jury's infringement verdict" are too late).

Factor 8. CoreValve Was Motivated to Take Sales Away from Edwards

CoreValve's motivation was clear. [redacted]

The evidence established that CoreValve took sales away from Edwards, and then sold the business to a larger, deep-pocket company that could fight the infringement lawsuit that

resulted. It was not an accident that CoreValve took over $70 million dollars in profits from Edwards. That was its plan from the beginning. Such conduct supports enhanced damages. *See nCUBE Corp.*, 313 F. Supp. 2d at 390 (infringement by "direct competitor[]" in "a highly competitive market" "militates in favor of enhanced damages").

Factor 9. CoreValve Concealed Its Misconduct Before Selling Its Generation 3 Devices

According to CoreValve, in the fall of 2004, it set up its U.S. facility and manufactured its first Generation 2 prototype. Terranova Decl., Ex. T (Kinrich Timeline). In March 2005, CoreValve manufactured its first batch of clinical-grade Generation 2 devices. *Id.* The next month, April 2005, Edwards sent its warning letter asking for an explanation. *Id.*, Ex. D (PTX 155).

Undaunted, and without responding, CoreValve plowed ahead. The Generation 3 device followed in 2006. Then CE approval in Europe in 2007. [redacted] Until this lawsuit began in 2008, CoreValve was able to conceal from Edwards the extent of its misconduct.

By concealing its infringing conduct until it marketed its infringing device, CoreValve gained significant benefits. CoreValve "locked up" doctors and hospitals before Edwards did, fulfilled its $700+ million "exit strategy" and attracted a deep-pocket company to fund an aggressive defense. TT at 566:8-16, 981:1-7, 981:24-982:1. The benefits CoreValve gained from its illegal conduct, and its concealment thereof, warrant enhanced damages, to prevent such misconduct in the future.

III. CONCLUSION

In sum, the jury's verdict of willfulness, as well as all nine *Read* factors, favor enhanced damages. On such a record, Edwards respectfully requests treble damages. In similar cases, where the factors are so heavily weighted toward the patent-holder, courts have granted treble damages. *E.g.*, *Advanced Med. Optics, Inc.* v. *Alcon Labs., Inc.*, Civ. A. No. 03-1095-KAJ, 2005 U.S. Dist. LEXIS 33378, at *29-32 (D. Del. Dec. 16, 2005) ("Based on the evidence of copying of [plaintiff's patents], the lack of appropriate investigation of [one] patent, and the amount of [defendant's] sales, I conclude that the damages award should be trebled."

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I hereby certify that on May 12, 2010 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

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I further certify that I caused copies of the foregoing document to be served on May 12, 2010 upon the following in the manner indicated:

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